DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 9/17/09. Claims 1-38 are canceled. Claim 39 has been amended. Claims 52-62 are newly added. Claims 39-62 are pending.

Claim Rejections - 35 USC § 101

2. The rejection of claims 39-51 under 35 U.S.C. 101 is hereby withdrawn due to the amendment filed 9/17/09.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (US 2002/0022776 A1) in view of Haller et al. (US 2001/0051787 A1).

(A) Referring to claim 39, Bardy discloses a method for automatically validating medical data received via a communication network, comprising (abstract of Bardy):

receiving a data set from an implantable medical device via a data input device (para. 13 and Fig. 1 of Bardy);

analyzing the data set from the implantable medical device with a data processor to determine implantable medical device configuration parameters (para. 11, 13, and 43 of Bardy); and

determining whether the implantable medical device configuration parameters are configured properly (para. 44, Fig. 11, and para. 62 of Bardy).

Bardy does not disclose comparing the implantable medical device configuration parameters to predefined clinical trial configuration parameters with the data processor.

Haller discloses comparing the implantable medical device configuration parameters to predefined clinical trial configuration parameters with the data processor (para. 197, para. 184, para. 177, Fig. 9C-1 and Fig. 9C-2 of Haller).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Haller within Bardy. The motivation for doing so would have been to reduce patient, clinical study, and overall healthcare costs (para. 197 of Haller).

(B) Referring to claim 40, Bardy discloses notifying a physician to reconfigure the implantable medical device if it is configured improperly (para. 44 of Bardy).

(C) Referring to claim 41, Bardy discloses wherein the physician is notified to reconfigure the implantable medical device electronically (para. 44 of Bardy).

5. Claims 42-43, 52, 57, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (US 2002/0022776 A1) in view of Haller et al. (US 2001/0051787 A1), and further in view of Krichen et al. (6,250,309).

(A) Referring to claims 42 and 43, Bardy and Haller do not disclose wherein the data set from the implantable medical device is received in a first data format, and wherein the method further comprises: converting the data set from the first data format to a second data format; and validating the second data format against the first data format to verify that the conversion from the first data format to the second data format occurred without errors and wherein the first data format comprises a binary data format, and the second data format comprises an extensible mark-up language (XML) data format.

Krichen discloses wherein the data set from the implantable medical device is received in a first data format, and wherein the method further comprises: converting the data set from the first data format to a second data format (col. 2, lines 52-61 of Krichen); and validating the second data format against the first data format to verify that the conversion from the first data format to the second data format occurred without errors (col. 2, lines 31-61 and col. 13, lines 27-43 of Krichen) and wherein the first data format comprises a binary data format, and the second data format comprises an extensible mark-up language (XML) data format (col. 2, lines 52-61 of Krichen).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Krichen within Bardy and

Haller. The motivation for doing so would have been to provide a format that can be manipulated at a remote location (col. 2, lines 31-36 of Krichen).

(B) Referring to claim 52, Bardy discloses a method for automatically validating medical data received via a communication network, comprising (abstract of Bardy):

receiving a data set in a first data format from an implantable medical device via a data input device (para. 13 and Fig. 1 of Bardy);

analyzing the data set from the implantable medical device with a data processor to determine implantable medical device configuration parameters (para. 11, 13, and 43 of Bardy);

determining whether the implantable medical device configuration parameters are configured properly (para. 44, Fig. 11, and para. 62 of Bardy); and

notifying a physician to reconfigure the implantable medical device if it is configured improperly (para. 44 of Bardy).

Bardy does not disclose comparing the implantable medical device configuration parameters to predefined clinical trial configuration parameters with the data processor, converting the data set from the first data format to a second data format; and validating the second data format against the first data format to verify that the conversion from the first data format to the second data format occurred without errors.

Haller discloses comparing the implantable medical device configuration parameters to predefined clinical trial configuration parameters with the data processor (para. 197, para. 184, para. 177, Fig. 9C-1 and Fig. 9C-2 of Haller).

Krichen discloses converting the data set from the first data format to a second data format (col. 2, lines 52-61 of Krichen); and validating the second data format against the first data format to verify that the conversion from the first data format to the second data format occurred without errors (col. 2, lines 31-61 and col. 13, lines 27-43 of Krichen)

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Haller and Krichen within Bardy. The motivation for doing so would have been to reduce patient, clinical study, and overall healthcare costs (para. 197 of Haller) and to provide a format that can be manipulated at a remote location (col. 2, lines 31-36 of Krichen).

(C) Referring to claim 57, Bardy discloses wherein the physician is notified to reconfigure the implantable medical device electronically (para. 44 of Bardy).

(D) Referring to claim 58, Bardy and Haller do not disclose wherein the first data format comprises a binary data format, and the second data format comprises an extensible mark-up language (XML) data format.

Krichen discloses wherein the first data format comprises a binary data format, and the second data format comprises an extensible mark-up language (XML) data format (col. 2, lines 52-61 of Krichen).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Krichen within Bardy and

Haller. The motivation for doing so would have been to provide a format that can be manipulated at a remote location (col. 2, lines 31-36 of Krichen).

6. Claims 44-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (US 2002/0022776 A1) in view of Haller et al. (US 2001/0051787 A1), and further in view of Boone et al. (US 2004/0243545 A1).

(A) Referring to claim 44, Bardy and Haller do not disclose receiving a data set comprising patient information entered by a physician; validating at least a portion of the patient information data set against validation parameters to determine if the entered patient information contains errors; prompting the physician to correct one or more errors if one or more errors exist, wherein after the one or more errors are corrected, the patient information is validated; and storing the validated patient information.

Boone discloses receiving a data set comprising patient information entered by a physician (para. 45 of Boone); validating at least a portion of the patient information data set against validation parameters to determine if the entered patient information contains errors (para. 46-48 of Boone); prompting the physician to correct one or more errors if one or more errors exist, wherein after the one or more errors are corrected, the patient information is validated (para. 46-48 of Boone); and storing the validated patient information (para. 48 of Boone).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Boone within Bardy and Haller. The motivation for doing so would have been to verify the information and provide a database with accurate information (para. 48 of Boone).

(B) Referring to claim 45, Bardy and Haller do not disclose wherein the patient information is validated during a patient data entry session.

Boone discloses wherein the patient information is validated during a patient data entry session (abstract and para. 28 of Boone).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Boone within Bardy and Haller. The motivation for doing so would have been to make corrections consistently (abstract and para. 28 of Boone).

(C) Referring to claim 46, Bardy discloses wherein the patient information is selected from the group consisting of objective patient information, subjective patient information, and patient diagnosis information (para. 63 of Bardy).

(D) Referring to claim 47, Bardy and Haller do not disclose wherein the patient information data set comprises data associated with one or more fields, and wherein the validation parameters comprise validation rules for the one or more fields.

Boone discloses wherein the patient information data set comprises data associated with one or more fields, and wherein the validation parameters comprise validation rules for the one or more fields (para. 71-72 of Boone).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Boone within Bardy and Haller. The motivation for doing so would have been to provide a standard format (para. 72 of Boone).

(E) Referring to claim 48, Bardy and Haller do not disclose receiving a data set comprising patient information entered by a physician; validating at least a portion of the patient information data set against patient information previously stored in a database to determine if any portion of the entered patient information is inconsistent with the stored patient information; and prompting the physician to verify that the entered patient information is accurate and correct any entered patient information that is determined to not be accurate if inconsistencies are located.

Boone discloses receiving a data set comprising patient information entered by a physician (para. 45 of Boone); validating at least a portion of the patient information data set against patient information previously stored in a database to determine if any portion of the entered patient information is inconsistent with the stored patient information (para. 46-48 of Boone); and prompting the physician to verify that the entered patient information is accurate and correct any entered patient information that is determined to not be accurate if inconsistencies are located (para. 29 and para. 46-48 of Boone).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Boone within Bardy and Haller.

The motivation for doing so would have been to verify the information and provide a database with accurate information (para. 48 of Boone).

7. Claims 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (US 2002/0022776 A1) in view of Haller et al. (US 2001/0051787 A1), in view of Boone et al. (US 2004/0243545 A1), and further in view of Sullivan (US 2002/0077865 A1).

(A) Referring to claim 49, Bardy, Haller, and Boone do not disclose wherein the patient information data set comprises data associated with a plurality of fields, the plurality of fields including a first field to receive a first measurement value for a patient symptom test and a second field to receive a second measurement value for the patient symptom test, and wherein the method further comprises: validating that the second field includes the second measurement value; and prompting the physician to enter the second measurement value into the second field if the second field does not include the second measurement value.

Sullivan discloses wherein the patient information data set comprises data associated with a plurality of fields, the plurality of fields including a first field to receive a first measurement value for a patient symptom test and a second field to receive a second measurement value for the patient symptom test, and wherein the method further comprises: validating that the second field includes the second measurement

value; and prompting the physician to enter the second measurement value into the second field if the second field does not include the second measurement value (Fig. 2, Fig. 17, para. 29, and para. 129 of Sullivan).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Sullivan within Bardy, Haller, and Boone. The motivation for doing so would have been to include the important or critical elements of documentation of a patient's particular medical condition in the medical record (para. 29 of Sullivan).

(B) Referring to claim 50, Bardy, Haller, and Boone do not disclose validating the second field against the first field to determine if the second measurement value is reasonable in view of the first measurement value; and if the second measurement value is not reasonable in view of the first measurement value, prompting the physician to verify the first measurement value, verify the second measurement value, enter a new first measurement value, or enter a new second measurement value.

Sullivan discloses validating the second field against the first field to determine if the second measurement value is reasonable in view of the first measurement value; and if the second measurement value is not reasonable in view of the first measurement value, prompting the physician to verify the first measurement value, verify the second measurement value, enter a new first measurement value, or enter a new second measurement value (para. 99, para. 121, para. 128, and para. 131 of Sullivan).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Sullivan within Bardy, Haller, and Boone. The motivation for doing so would have been so that the symptoms presented by the patient are properly and quickly evaluated and documented (para. 99 of Sullivan).

8. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (US 2002/0022776 A1) in view of Haller et al. (US 2001/0051787 A1), and further in view of Joyce et al. (US 2001/0053984 A1).

(A) Referring to claim 51, Bardy and Haller do not disclose receiving a data set comprising subjective patient information entered by a physician; and normalizing the subjective information to adjust for physician biases.

Joyce discloses receiving a data set comprising subjective patient information entered by a physician; and normalizing the subjective information to adjust for physician biases (para. 5, para. 44, para. 49-52 of Joyce).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Joyce within Bardy and Haller. The motivation for doing so would have been to assess treatment protocols (para. 7 of Joyce).

9. Claims 53 and 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (US 2002/0022776 A1) in view of Haller et al. (US 2001/0051787 A1), in view of Krichen et al. (6,250,309), and further in view of Boone et al. (US 2004/0243545 A1).

(A) Referring to claim 53, Bardy, Haller, and Krichen do not disclose receiving a data set comprising patient information entered by a physician; validating at least a portion of the patient information data set against patient information previously stored in a database to determine if any portion of the entered patient information is inconsistent with the stored patient information; and prompting the physician to verify that the entered patient information is accurate and correct any entered patient information that is determined to not be accurate if inconsistencies are located.

Boone discloses receiving a data set comprising patient information entered by a physician (para. 45 of Boone); validating at least a portion of the patient information data set against patient information previously stored in a database to determine if any portion of the entered patient information is inconsistent with the stored patient information (para. 46-48 of Boone); and prompting the physician to verify that the entered patient information is accurate and correct any entered patient information that is determined to not be accurate if inconsistencies are located (para. 29 and para. 46-48 of Boone).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Boone within Bardy, Haller,

and Krichen. The motivation for doing so would have been to verify the information and provide a database with accurate information (para. 48 of Boone).

(B) Referring to claim 59, Bardy, Haller, and Krichen do not disclose receiving a data set comprising patient information entered by a physician; validating at least a portion of the patient information data set against validation parameters to determine if the entered patient information contains errors; prompting the physician to correct one or more errors if one or more errors exist, wherein after the one or more errors are corrected, the patient information is validated; and storing the validated patient information.

Boone discloses receiving a data set comprising patient information entered by a physician (para. 45 of Boone); validating at least a portion of the patient information data set against validation parameters to determine if the entered patient information contains errors (para. 46-48 of Boone); prompting the physician to correct one or more errors if one or more errors exist, wherein after the one or more errors are corrected, the patient information is validated (para. 46-48 of Boone); and storing the validated patient information (para. 48 of Boone).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Boone within Bardy, Haller, and Krichen. The motivation for doing so would have been to verify the information and provide a database with accurate information (para. 48 of Boone).

(C) Referring to claim 60, Bardy, Haller, and Krichen do not disclose wherein the patient information is validated during a patient data entry session.

Boone discloses wherein the patient information is validated during a patient data entry session (abstract and para. 28 of Boone).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Boone within Bardy, Haller, and Krichen. The motivation for doing so would have been to make corrections consistently (abstract and para. 28 of Boone).

(D) Referring to claim 61, Bardy discloses wherein the patient information is selected from the group consisting of objective patient information, subjective patient information, and patient diagnosis information (para. 63 of Bardy).

(E) Referring to claim 62, Bardy, Haller, and Krichen do not disclose wherein the patient information data set comprises data associated with one or more fields, and wherein the validation parameters comprise validation rules for the one or more fields.

Boone discloses wherein the patient information data set comprises data associated with one or more fields, and wherein the validation parameters comprise validation rules for the one or more fields (para. 71-72 of Boone).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Boone within Bardy, Haller, and Krichen. The motivation for doing so would have been to provide a standard format (para. 72 of Boone).

10. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (US 2002/0022776 A1) Haller et al. (US 2001/0051787 A1), in view of Krichen et al. (6,250,309), and further in view of Joyce et al. (US 2001/0053984 A1).
(A) Referring to claim 56, Bardy, Haller, and Krichen do not disclose receiving a data set comprising subjective patient information entered by a physician; and normalizing the subjective information to adjust for physician biases.

Joyce discloses receiving a data set comprising subjective patient information entered by a physician; and normalizing the subjective information to adjust for physician biases (para. 5, para. 44, para. 49-52 of Joyce).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Joyce within Bardy, Haller, and Krichen. The motivation for doing so would have been to assess treatment protocols (para. 7 of Joyce).

11. Claims 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (US 2002/0022776 A1) in view of Haller et al. (US 2001/0051787 A1), in view of Krichen et al. (6,250,309), in view of Boone et al. (US 2004/0243545 A1), and further in view of Sullivan (US 2002/0077865 A1).
(A) Referring to claim 54, Bardy, Haller, Krichen, and Boone do not disclose wherein the patient information data set comprises data associated with a plurality of fields, the

plurality of fields including a first field to receive a first measurement value for a patient symptom test and a second field to receive a second measurement value for the patient symptom test, and wherein the method further comprises: validating that the second field includes the second measurement value; and prompting the physician to enter the second measurement value into the second field if the second field does not include the second measurement value.

Sullivan discloses wherein the patient information data set comprises data associated with a plurality of fields, the plurality of fields including a first field to receive a first measurement value for a patient symptom test and a second field to receive a second measurement value for the patient symptom test, and wherein the method further comprises: validating that the second field includes the second measurement value; and prompting the physician to enter the second measurement value into the second field if the second field does not include the second measurement value (Fig. 2, Fig. 17, para. 29, and para. 129 of Sullivan).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Sullivan within Bardy, Haller, Krichen, and Boone. The motivation for doing so would have been to include the important or critical elements of documentation of a patient's particular medical condition in the medical record (para. 29 of Sullivan).

(B) Referring to claim 55, Bardy, Haller, Krichen, and Boone do not disclose validating the second field against the first field to determine if the second measurement value is

reasonable in view of the first measurement value; and if the second measurement value is not reasonable in view of the first measurement value, prompting the physician to verify the first measurement value, verify the second measurement value, enter a new first measurement value, or enter a new second measurement value.

Sullivan discloses validating the second field against the first field to determine if the second measurement value is reasonable in view of the first measurement value; and if the second measurement value is not reasonable in view of the first measurement value, prompting the physician to verify the first measurement value, verify the second measurement value, enter a new first measurement value, or enter a new second measurement value (para. 99, para. 121, para. 128, and para. 131 of Sullivan).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Sullivan within Bardy, Haller, Krichen, and Boone. The motivation for doing so would have been so that the symptoms presented by the patient are properly and quickly evaluated and documented (para. 99 of Sullivan).

Response to Arguments

12. Applicant's arguments with respect to claim 39 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LENA NAJARIAN whose telephone number is (571) 272-7072. The examiner can normally be reached on Monday - Friday, 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

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Examiner, Art Unit 3686
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/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686